IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

LISA A. WEBB Plaintiffs, vs. COOK GROUP, INC.; COOK INCORPORATED; COOK BIOTECH, INC; COOK UROLOGICAL INCORPORATED; COOK MEDICAL INC., Defendants.	)	Case No.: 2:13-cv-17053 (MDL 2440) **JURY TRIAL DEMANDED**

PLAINTIFF'S ORIGINAL COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, by and through her undersigned counsel, brings this Complaint for damages against Defendants and in support thereof state the following:

1. This is a device tort action brought on behalf of the above named Plaintiff arising out of the negligence, negligent misrepresentation, breach of warranty and strict liability of the Defendants in their manufacture, promotion, distribution, sale and/or provision of incomplete, inaccurate information related to its transvaginal mesh products. As a result, Plaintiff LISA A. WEBB suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. The Plaintiff respectfully seeks all damages to which she may be legally entitled.

By order of June 11, 2013, the United States Judicial Panel on Multidistrict Litigation has consolidated pretrial proceedings involving Defendants' transvaginal mesh products into MDL No. 2440 in this Court. Plaintiff's claims are appropriate for inclusion in this consolidated proceeding.

I. PARTIES

2. Plaintiff LISA A. WEBB is, and was, at all relevant times, a resident and citizen of Butler, Indiana.

3. Defendant Cook Group, Inc. is a corporation organized under the laws of Indiana, with a principal place of business at 750 N. Daniels Way, Bloomington, Indiana 47404-9120. Cook Group Incorporated was allegedly founded to help manage financial, legal and regulatory issues that emerged as the COOK companies expanded in the United States and abroad. http://www.cookmedical.com/profile.do?id=profile_cookgroup. All acts and omissions of Cook Group, Inc. as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

4. Defendant Cook Incorporated is a corporation organized under the laws of Indiana, with a principal place of business at 750 Daniels Way, P.O. Box 489, Bloomington, Indiana 47402. Cook Incorporated is allegedly also on the forefront of developing next generation technologies that advance combination drug/device and biologic/device design concepts. http://www.cookmedical.com/profile.do?id=profile_cookinc. All acts and omissions of Cook Incorporated, Inc. as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

5. Defendant Cook Biotech, Inc. is a corporation organized under the laws of Indiana, with a principal place of business at 1425 Innovation Place, West Lafayette, Indiana 47906. Cook Biotech was allegedly created to develop and manufacture biomaterials from natural tissue sources for use in medical products. The company purports to conduct research,

development and manufacturing operations in a state-of-the-art facility. Cook Biotech operates its own processing and production line where natural tissues are transformed into acellular biomaterials. In cooperation with university researchers, Cook Biotech has developed a line of products that can remodel native tissues using a biomaterial made from porcine small intestinal submucosa (SIS). Several FDA-cleared products using this technology to dress wounds or to surgically repair soft tissues are currently available from COOK and its distributors. Numerous potential medical applications for products made from SIS and other natural tissues are under development. http://www.cookmedical.com/profile.do?id=profile_biotech. All acts and omissions of Cook Group, Inc. as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

6. Defendant Cook Urological Incorporated is a corporation organized under the laws of Indiana, with a principal place of business at 1100 West Morgan Street, P.O. Box 227, Spencer, IN 47460 Cook Urological is the global sales and marketing headquarters for the Urological and Women's Health strategic business units. Cook Urological was allegedly established to provide professionals in urologic healthcare with minimally invasive diagnostic and therapeutic technology. The company is recognized worldwide for innovation in stone management, diagnostic and therapeutic products for the urinary system, and biomaterials for the treatment of stress urinary incontinence. http://www.cookmedical.com/profile.do?id=profile_uro. All acts and omissions of Cook Urological Incorporated as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

7. Defendant Cook Medical, Inc. is a corporation organized under the laws of Indiana, with a principal place of business at 1025 W. Acuff Road, Bloomington, Indiana 47402-4195. Cook Medical Incorporated was allegedly established to offer a synchronized service for the efficient purchase and distribution of all Cook medical devices. With particular focus on lowering supply chain costs, the company coordinates price file access, purchase orders, ship points and accounts payable. http://www.cookmedical.com/profile.do?id=profile_cmi. All acts and omissions of Cook Medical, Inc. as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

8. Upon information and belief, the Cook Defendants individually or collectively make, use, offer for sale, sell in the United States, and/or import into the United States products used to treat pelvic organ prolapse and stress urinary incontinence including the Surgisis Biodesign system or line of pelvic products and related delivery devices.

9. Upon information and belief, Defendant Cook Group, Inc. is the parent company for all other named Defendants and did the following through its subsidiaries named herein: designed; secured clearance for sale; manufactured; labeled; marketed; distributed; sold; benefited financially from the sale; and placed into the stream of commerce the products implanted in Plaintiff. Defendants, as such, are individually, jointly and severally liable to Plaintiff.

10. Upon information and belief, and upon review of Defendants own combined website, Plaintiff asserts that the following Defendants participated in placing the product implanted in Plaintiff into the stream of commerce causing her injuries: Cook Group, Inc. is the parent and nerve center of the Cook operations which, through its subsidiaries designed, tested,

sought regulatory clearance, marketed, advertised, labeled, distributed and sold the subject medical device; Defendant Cook Incorporated participated in the development of the subject medical device; Defendant Cook Biotech, Inc. developed, with the aid of other co-Defendants, manufactured, sought regulatory clearance, marketed, advertised, labeled, distributed and sold the subject medical device; Defendant Cook Urological Incorporated with the aid of other co-Defendants, manufactured, sought regulatory clearance, marketed, advertised, labeled, distributed and sold biomaterials for the treatment of stress urinary incontinence including the subject medical device; and Defendant Cook Medical, Inc. were the central and key agent in the distribution of Plaintiff's medical device.

11. Defendants COOK GROUP, INC., COOK INCORPORATED, COOK BIOTECH, IN., COOK UROLOGICAL INCORPORATED and COOK MEDICAL INC. share many of the same officers, directors and operations; and maintain ownership in the assets and/or liabilities relating to the design, manufacture, marketing, distribution and sale of the medical device line at issue in this litigation and shall be referenced collectively hereinafter as "Cook Defendants".

12. All acts and omissions of each Defendant as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

II. JURISDICTION AND VENUE

13. Damages sought in this matter are in excess of $75,000.00.

14. By order of June 11, 2013, the United States Judicial Panel on Multidistrict Litigation has consolidated pretrial proceedings involving Defendants' transvaginal mesh products into MDL No. 2440 in this Court.

15. Venue is proper as Cook Defendants reside in this District and regularly conduct business in this state. Defendants are subject to personal jurisdiction of this judicial district. By order of June 11, 2013, the United States Judicial Panel on Multidistrict Litigation has consolidated pretrial proceedings involving Defendants' transvaginal mesh products into MDL No. 2440 in this Court.

III. DEFENDANTS' PELVIC MESH PRODUCTS

Cook Defendants Products

16. In or about 1999, Defendants began to market and sell products for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence.

17. Specifically, Cook Group, Incorporated, by and through its subsidiary, Cook Biotech, Inc., sought and secured 510K clearance on the following medical devices indicated and/or sold for the repair or restoration of stress urinary incontinence: Surgisis Biodesign Urethral Sling on September 23, 1999 and Surgisis Biodesign Tension-Free Urethral Sling on April 9, 2002. Cook Biotech, Inc. sought and secured 510K clearance on the following medical devices indicated and/or sold for the repair or restoration of pelvic floor repair: Surgisis Biodesign Anterior Pelvic Floor Graft; Surgisis Biodesign Posterior Pelvic Floor Graft; and Surgisis Biodesign Vaginal Erosion Repair Graft on September 23, 1999.

18. Defendants' products were derived largely from hernia mesh products, and were and are utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence.

19. Defendants' Pelvic Mesh Products were designed, patented, manufactured, labeled, marketed, and sold and distributed by the Defendants, at all times relevant herein.

20. Defendants' make the following assertions regarding their products:

Surgisis Biodesign is not a new- graft or mesh, but a whole new category in the evolution of tissue repair. A breakthrough technology, it incorporates the best attributes of a biologic graft—resistant to infection and complete remodeling—with the added benefits of moderate price, ease of use and widespread availability. Surgisis Biodesign offers you a new level of assurance and, most important, contributes to an improved quality of life for your patient. http://www.cookmedical.com/bioNew/bio_overview.html.

21. Defendants' further assert the following about their Biodesign products: "And unlike synthetic mesh, **nothing is left permanently in the body to cause problems down the road**." http://www.cookbiodesign.com/for-patients/conditions/fistula/faqs.

22. On August 20, 2011, Defendants issued a communication to the FDA in advance of the September 2011 Advisory Committee Hearings regarding the investigation into the risks associated with mesh for stress urinary incontinence and pelvic floor repair and/or pelvic floor prolapse. In its communication, Defendants assert regarding its non-cross linked biologic matrix that: **"[a]ny inflammation is localized in regions where small remnants of the synthetic suture used to affix the graft remain**."

23. Contrary to Defendants assertions that its products are resistant to infection, result in complete remodeling, are limited in inflammatory response to area where synthetic sutures are/were utilized during surgery and will not cause any problem down the road, the following non-inclusive literature suggests otherwise:

A. In November of 2005, results from a study were published in the International Journal of Obstetrics & Gynecology relating to the comparison of the host response, architectural integration and tensile strength of polypropylene

to porcine small intestine submucosa-derived implants including Defendants SIS products. Implants from the SIS group showed a short term increase in thickness in the first 14 days. Formation of adhesions was significantly more extensive in the SIS group at 90 days. Tensile strength increased over time in both groups but was significantly lower in the SIS group. Implants in the SIS group showed inflammatory response.

Konstantinovic ML., Lagae P., Zheng F., Verbeken EK., De Ridder D., Deprest JA. (2005). Comparison of host response to polypropylene and non-cross-linked porcine small intestine serosal-derived collagen implants in a rat model. *BJOG: An International Journal of Obstetrics & Gynecology,* 112(11),1554-1560.

B. In October of 2008, results from a study were published in the Archives of Gastroenterology relating to the comparison of the repair of induced abdominal wall defects with Defendants' Surgisis mesh and Covidien, Inc.'s Parietex. Both meshes induced skin erosions. There were peritoneal adhesions to the surface of both types of meshes after 30 and 60 days**. Meshes' shrinking correspond to 1/3 of the original size and Parietex caused less inflammatory process at the histologic evaluation**.

Baroncello JB., Czeczko NG., Malafaia O., Ribas-Filho JM., Nassif PA., Dietz AU. (2008). [The repair of abdominal defects in rabbits with Parietex and Surgisis meshes abdominal wall]. *Arquivos de Gastroenterologia*, 45(4), 323-9.

C. In November of 2008, results from a study were published in Urology relating to reports of intense local inflammatory reactions in patients undergoing

pubovaginal sling or tape using a small intestinal submucosa graft. After implantation of 16 standard pubovaginal sling or tension-free tape procedures for stress urinary incontinence, using the Cook 4-ply Stratasis or 8-ply Stratasis-TF system, 5 (31.3%) had intense suprapubic pain after surgery. One patient had induration of the mons pubis that required surgical drainage. One patient had vaginal inflammation, with expulsion of graft material. Other patients had intense rectus sheath inflammation, as confirmed on computed tomography. This study confirmed previous case reports of inflammatory complications of small intestinal submucosa leading to that institution's cessation of use of Defendants' products.

John TT., Aggarwal N., Singla AK., Santucci RA. (2008). Intense inflammatory reaction with porcine small intestine submucosa pubovaginal sling or tape for stress urinary incontinence. *Urology*, 72(5), 1036-9.

D. In January of 2009, results from a study were published in the Journal of Biomedical Materials Research Part B relating to the evaluation of Defendants' Surgisis Gold to other materials including C.R. Bard, Inc.'s Permacol; Ethicon's Prolene mesh and Life Cell's Alloderm in the context of human mesothelial cells. The results of the study indicate that Surgisis Gold was inferior in aiding in the growth and fibrinolytic activity of human mesothelial cells than other products.

Wilshaw SP., Burke D., Fisher J., Ingham E. (2009). Investigation of the antiadhesive properties of human mesothelial cells cultured in vitro on implantable surgical materials. *Journal of Biomedical Materials Research Part D: Applied Biomaterials*, 88(1), 49-60.

E. In October of 2011, results from a study were published in the Archives of Gastroenterology relating to the comparison of different biologic materials regarding relative implant integration, shrinkage, and foreign body reaction. Relating to **Defendants' Surgisis, the integration of its product was insufficient and could detached easily from the underlying tissue; the penetration of fibroblasts and vessels was limited; foreign body reaction was pronounced, leading to persistent granulomatous inflammation; and shrinkage was excessive in comparison to all other products. Other products yielded sufficient anti-adhesion and elicited no foreign body reaction**.

Petter-Puchner AH., Fortelny RH., Silic K, Brand J., Gruber-Blum S., Redl H. (2011). Biologic hernia implants in experimental intraperitoneal onlay mesh plasty repair: the impact of proprietary collagen processing methods and fibrin sealant application on tissue integration. *Surg Endosc*, 25(10), 3245-52.

F. In February of 2012, results from a study were published in Hernia relating to the comparison of different biologic meshes including Defendants' Surgisis Gold regarding the relative performance and efficacy as between two non-crosslinked meshes and two crosslinked prostheses. Major complications seen with Defendants' product included: that it appeared to be wrinkled and folded by excessive shrinkage, eliciting severe adhesions and a pronounced local inflammation, characterized by foreign body giant cells. The multilayer design was preserved but disintegrated by transversal movement of layers against each other.

de Castro Brás LE., Shurey, S., Sibbons, PD. (2012). Evaluation of crosslinked and non-crosslinked biologic prostheses for abdominal hernia repair. *Hernia,* 16(1), 77-89.

G. In September of 2012, results from a study were published in Biomaterials relating to the clinical performance of biomaterials in the context of comparing leukocyte activation by commercially available biologic surgical materials and define the extent manufacturing variables influence down-stream response. **The data demonstrated Defendants' Surgisis Biodesign which was implanted in Plaintiff showed excessive leukocyte activation and was significantly more pro-inflammatory as compared to the other products analyzed. High degrees of leukocyte activation lead to poor material/patient compliance, accelerated degeneration and graft rejection**.

Bryan N., Ashwin H., Smart N., Bayon Y., Scarborough N., Hunt JA. (2012). The innate oxygen dependent immune pathway as a sensitive parameter to predict the performance of biological graft materials. *Biomaterials,* 33(27), 6380-92.

24. Defendants' Pelvic Mesh Products were designed, patented, manufactured, labeled, marketed, and sold and distributed by the Defendants, at all times relevant herein.

IV. FACTUAL BACKGROUND

25. On or about April 11, 2005, Plaintiff was implanted with the Surgisis Biodesign Urethral Sling - ("Pelvic Mesh Products" and/or "Product") during surgery performed at DeKalb Memorial Hospital in Auburn, Indiana.

26. The Product was implanted in Plaintiff to treat mixed urinary incontinence, a use for which the Product was designed, marketed and sold.

27. As a result of having the Products implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, permanent and substantial physical deformity, will be undergoing corrective surgery or surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and present and future lost wages.

28. Defendants Pelvic Mesh Products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily pelvic organ prolapse and stress urinary incontinence, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing pelvic mesh products.

29. The Defendants have marketed and sold the Defendants Pelvic Mesh Products to the medical community at large and patients through carefully planned, multi faceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and include the provision of valuable consideration and benefits to health care providers. Also utilized are documents, brochures, websites, and telephone information lines, offering exaggerated and misleading expectations as to the safety and utility of the Defendants' Pelvic Mesh Products.

30. Contrary to the Defendants' representations and marketing to the medical community and to the patients themselves, the Defendants' Pelvic Mesh Products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often

debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff.

31. The Defendants have consistently underreported and withheld information about the propensity of Defendants' Pelvic Mesh Products to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Products, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

32. Defendants have known and continue to know that their disclosures to the FDA were and are incomplete and misleading; and that the Defendants' Pelvic Mesh Products were and are causing numerous patients severe injuries and complications. The Defendants suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, or the patients. As a result, the Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the Defendants' Pelvic Mesh Products were and are safe and effective, leading to the prescription for and implantation of the Pelvic Mesh Products into the Plaintiff.

33. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Defendants Pelvic Mesh Products.

34. Defendants failed to design and establish a safe, effective procedure for removal of the Defendants' Pelvic Mesh Products; therefore, in the event of a failure, injury, or complications it is impossible to easily and safely remove the Defendants' Pelvic Mesh Products.

35. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation and treatment of stress urinary incontinence, pelvic organ

prolapse, and similar other conditions have existed at all times relevant as compared to the Defendants' Pelvic Mesh Products.

36. The Defendants Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to the Defendants.

37. The Defendants have at all times provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Defendants' Pelvic Mesh Products, and thus increase the sales of the Products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

38. The Pelvic Mesh Products implanted into the Plaintiff was in the same or substantially similar condition as they were when they left the possession of Defendants, and in the condition directed by and expected by the Defendants.

39. The injuries, conditions, and complications suffered due to Defendants' Pelvic Mesh Products include but are not limited to mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, pelvic pain, urinary and fecal incontinence, prolapse of organs, and in many cases the women have been forced to undergo intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia, and injuries to Plaintiff's intimate partners.

40. Despite Defendants' knowledge of these catastrophic injuries, conditions, and complications caused by their Pelvic Mesh Products, the Defendants have, and continue to manufacture, market, and sell the Products, while continuing to fail to adequately warn, label, instruct, and disseminate information with regard to the Defendants' Pelvic Mesh Products, both prior to and after the marketing and sale of the Products.

41. Plaintiff in the exercise of due diligence, could not have reasonably discovered the cause of her injuries including but not limited to the defective design and/or manufacturing of the products implanted inside of her until recently.

COUNT I

PRODUCTS LIABILITY - FAILURE TO WARN

42. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

43. Under Indiana law, a product is defective if the seller fails to properly package or label the product to give reasonable warnings of danger about the product or fails to give reasonably complete instructions on proper use of the product when the seller, by exercising reasonable diligence, could have made such warnings or instructions available to the user or consumer.

44. The Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers as to the proper candidates for use the Defendants' Pelvic Mesh Products, and the safest and most effective methods of implantation and use of the Defendants' Pelvic Mesh Products. The Defendants failed to properly package or label the product to give reasonable warnings of danger about the product to Plaintiff and her health care providers.

45. The Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers as to the dangers of the Defendants' Pelvic Mesh Products, given the Plaintiff's conditions and need for information.

46. The Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers with regard to the inadequate research and testing of the Pelvic Mesh Products, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Products.

47. The Defendants acted with malice, fraud, gross negligence, or oppressiveness which was not the result of a mistake of fact or law, honest error or judgment, over zealousness, mere negligence, or other human failing in misrepresenting the safety, danger, risks, and benefits of the Defendants' Pelvic Mesh Products, understating the risks and exaggerating the benefits in order to advance their own financial interests, with reckless and/or heedless disregard for the consequences, including the safety and health of the Plaintiff.

48. As a proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiff has been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

49. The Defendants are strictly liable in tort to the Plaintiff for their wrongful conduct.

WHEREFORE, Plaintiff demands judgment against Defendants of compensatory damages, punitive damages, interest, attorneys' fees, costs of suit, and such further relief as the Court deems equitable and just.

COUNT II

PRODUCTS LIABILITY - DESIGN DEFECT

50. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

51. At the time of Plaintiff's injuries, the Defendants' Pelvic Mesh Products were in a defective condition because, at the time they were conveyed by Defendants to another party, the products were in a condition (a) not contemplated by reasonable persons among those considered expected users or consumers of the product, and (b) that will be unreasonably dangerous to the expected user or consumer when used in reasonably expectable ways of handling or consumption.

52. The Defendants acted with malice, fraud, gross negligence, or oppressiveness which was not the result of a mistake of fact or law, honest error or judgment, over zealousness, mere negligence, or other human failing in the design of Defendants' Pelvic Mesh Products, with reckless and/or heedless disregard for the consequences, including the safety and health of the Plaintiff.

53. As a proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiff has been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III

NEGLIGENCE

54. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

55. Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of the Defendants' Pelvic Mesh Products, and recruitment and training of physicians to implant the Pelvic Mesh Products.

56. Defendants breached their duty of care to the Plaintiff; as aforesaid, in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution, and recruitment and training of physicians to implant the Pelvic Mesh Products.

57. The Defendants acted with malice, fraud, gross negligence, or oppressiveness which was not the result of a mistake of fact or law, honest error or judgment, over zealousness, mere negligence, or other human failing n the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of the Defendants' Pelvic Mesh Products, and recruitment and training of physicians to implant the Pelvic Mesh Products, with reckless and/or heedless disregard for the consequences, including the safety and health of the Plaintiff.

58. As a proximate result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiff has been injured, often catastrophically, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages,

punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IV

NEGLIGENT MISREPRESENTATION

59. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

60. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the Pelvic Mesh Products had not been adequately tested and found to be safe and effective for the treatment of incontinence and prolapse. The representations made by Defendants, in fact, were false.

61. Defendants failed to exercise ordinary care in the representations concerning the Pelvic Mesh Products while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Pelvic Mesh Products' high risk of unreasonable, dangerous, adverse side effects.

62. Defendants breached their duty in representing that the Defendants' Pelvic Mesh Products have no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical and healthcare community.

63. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the Pelvic Mesh Products had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, erosion,

pain and suffering, surgery to remove the products, and other severe and personal injuries, which are permanent and lasting in nature.

64. The Defendants acted with malice, fraud, gross negligence, or oppressiveness which was not the result of a mistake of fact or law, honest error or judgment, over zealousness, mere negligence, or other human failing in misrepresenting the safety, danger, risks, and benefits of the Defendants' Pelvic Mesh Products, understating the risks and exaggerating the benefits in order to advance their own financial interests, with reckless and/or heedless disregard for the consequences, including the safety and health of the Plaintiff.

65. As a proximate result of the Defendants' conduct, Plaintiff has been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT V

BREACH OF EXPRESS WARRANTY

66. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

67. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' Pelvic Mesh Products.

68. At all relevant times, Defendants intended that the Defendants' Pelvic Mesh Products be used in the manner that Plaintiff in fact used them and Defendants expressly

warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other pelvic mesh products, and that it was adequately tested and fit for its intended use.

69. At all relevant times, Defendants were aware that consumers, including Plaintiff, would use the Pelvic Mesh Products; which is to say that Plaintiff was a foreseeable user of the Defendants' Pelvic Mesh Products.

70. Plaintiff and/or her implanting physicians were at all relevant times in privity with Defendants.

71. The Defendants' Pelvic Mesh Products were expected to reach and did in fact reach consumers, including Plaintiff and her implanting physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

72. Defendants breached various express warranties with respect to the Pelvic Mesh Products including the following particulars:

(a) Defendants represented to Plaintiff and her physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Pelvic Mesh Products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Pelvic Mesh Products;

(b) Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' Pelvic Mesh Products were as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which

demonstrated that the Products were not safer than alternatives available on the market; and

(c) Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' Pelvic Mesh Products were more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of the products.

73. In reliance upon Defendants' express warranty, Plaintiff was implanted with the Defendants' Pelvic Mesh Products as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

74. At the time of making such express warranties, Defendants knew or should have known that the Defendants' Pelvic Mesh Products do not conform to these express representations because the Defendants' Pelvic Mesh Products were not safe and had numerous serious side effects, many of which Defendants did not accurately warn about, thus making the Defendants' Pelvic Mesh Products unreasonably unsafe for their intended purpose.

75. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff and the Public relied upon the representations and warranties of Defendants in connection with the use recommendation, description, and/or dispensing of the Defendants' Pelvic Mesh Products.

76. Defendants breached their express warranties to Plaintiff in that the Defendants' Pelvic Mesh Products were not of merchantable quality, safe and fit for their intended uses, nor were they adequately tested.

77. The Defendants acted with malice, fraud, gross negligence, or oppressiveness which was not the result of a mistake of fact or law, honest error or judgment, over zealousness,

mere negligence, or other human failing in breaching their express warranties to Plaintiff with reckless and/or heedless disregard for the consequences, including the safety and health of the Plaintiff.

78. As a proximate result of the Defendants' conduct, Plaintiff has been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI

BREACH OF IMPLIED WARRANTY

79. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

80. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' Pelvic Mesh Products.

81. At all relevant times, Defendants intended that the Defendants' Pelvic Mesh Products be implanted for the purposes and in the manner that Plaintiff or Plaintiff's implanting physicians in fact used them and Defendants impliedly warranted each product to be of merchantable quality, safe and fit for such use, and was not adequately tested.

82. Defendants were aware that consumers, including Plaintiff or Plaintiff's physicians, would implant the Defendants' Pelvic Mesh Products in the manner directed by the

instructions for use; which is to say that Plaintiff were foreseeable users of the Defendants' Pelvic Mesh Products.

83. Plaintiff and/or her physicians were at all relevant times in privity with Defendants.

84. The Defendants' Pelvic Mesh Products were expected to reach and did in fact reach consumers, including Plaintiff or Plaintiff's physicians, without substantial change in the condition in which they were manufactured and sold by Defendants.

85. Defendants breached various implied warranties with respect to the Defendants' Pelvic Mesh Products, including the following particulars:

(a) Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Pelvic Mesh Products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Pelvic Mesh Products;

(b) Defendants represented that the Defendants' Pelvic Mesh Products were safe, and/or safer than other alternative devices or procedures and fraudulently concealed information, which demonstrated that the Defendants' Pelvic Mesh Products were not as safe or safer than alternatives available on the market; and

(c) Defendants represented that the Defendants' Pelvic Mesh Products were more efficacious than alternative pelvic mesh products and procedures and fraudulently concealed information, regarding the true efficacy of the Defendants' Pelvic Mesh Products.

86. In reliance upon Defendants' implied warranty, Plaintiff used the Pelvic Mesh Products as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

87. Defendants breached their implied warranty to Plaintiff in that the Defendants' Pelvic Mesh Products were not of merchantable quality, safe and fit for their intended use, or adequately tested.

88. The Defendants acted with malice, fraud, gross negligence, or oppressiveness which was not the result of a mistake of fact or law, honest error or judgment, over zealousness, mere negligence, or other human failing in breaching their implied warranties to Plaintiff with reckless and/or heedless disregard for the consequences, including the safety and health of the Plaintiff.

89. As a proximate result of the Defendants' conduct, Plaintiff has been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VII

VIOLATION OF CONSUMER PROTECTION LAWS – INDIANA DECEPTIVE CONSUMER SALES ACT

90. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

91. Plaintiff purchased and used the Defendants' Pelvic Mesh Products primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

92. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Defendants' Pelvic Mesh Products, and would not have incurred related medical costs and injury.

93. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the Pelvic Mesh Products that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

94. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a.) Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

b.) Advertising goods or services with the intent not to sell them as advertised; and,

c.) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

95. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Defendants' Pelvic Mesh Products. Each aspect of Defendants' conduct combined to artificially create sales of the Defendants' Pelvic Mesh Products.

96. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Defendants' Pelvic Mesh Products.

97. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Products, and would not have incurred related medical costs.

98. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the Indiana Deceptive Consumer Sales Act, Indiana Code section 24-5-0.5-1 *et seq.*

99. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of the Indiana Deceptive Consumer Sales Act, Indiana Code section 24-5-0.5-1 *et seq.*.

100. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the Indiana Deceptive Consumer Sales Act, Indiana Code section 24-5-0.5-1 *et seq.*

101. Under the Indiana Deceptive Consumer Sales Act, Indiana Code section 24-5-0.5-1 *et seq.*, which is intended, *inter alia*, to protect consumers from suppliers who commit deceptive and unconscionable sales acts, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under Indiana law for their deceptive and unconscionable consumer sales practices.

102. Defendants violated the Indiana Deceptive Consumer Sales Act, Indiana Code section 24-5-0.5-1 *et seq.*, by knowingly and falsely representing that the Defendants' Pelvic

Mesh Products were fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

103. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the Indiana Deceptive Consumer Sales Act, Indiana Code section 24-5-0.5-1 *et seq.*

104. Defendants had actual knowledge of the defective and dangerous condition of the Defendants' Pelvic Mesh Products and failed to take any action to cure such defective and dangerous conditions.

105. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

106. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

107. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

108. As a direct and proximate result of Defendants' violations of the Indiana Deceptive Consumer Sales Act, Indiana Code section 24-5-0.5-1 *et seq.*, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory, damages in an amount to be proven at trial as well as attorney's fees and costs as allowed by law.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of

profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT VIII

GROSS NEGLIGENCE

109. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

110. In acting as described above, Defendants acted with malice, fraud, gross negligence, or oppressiveness which was not the result of a mistake of fact or law, honest error or judgment, over zealousness, mere negligence, or other human failing with reckless and/or heedless disregard for the consequences, including the safety and health of the Plaintiff.

111. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IX

UNJUST ENRICHMENT

112. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

113. Defendants are and at all times were the manufacturers, sellers, and/or suppliers of the Defendants' Pelvic Mesh Products.

114. Plaintiff paid for the Defendants' Pelvic Mesh Products for the purpose of treatment of stress urinary incontinence and/or pelvic organ prolapse or other similar condition.

115. Defendants have accepted payment by Plaintiff and others on Plaintiff's behalf for the purchase of the Defendants' Pelvic Mesh Products.

116. Plaintiff has not received the safe and effective medical devices for which she paid.

117. It would be inequitable for Defendants to keep this money since Plaintiff did not in fact receive a safe and effective medical device.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT X

PUNITIVE DAMAGES

118. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

119. At all times relevant hereto, Defendants knew or should have known that the Defendants' Pelvic Mesh Products were inherently more dangerous with respect to the risks of erosion, failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the product, as well as other severe and personal injuries which are permanent and lasting in nature.

120. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the Defendants' Pelvic Mesh Products.

121. Defendants' misrepresentation included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the Defendants' Pelvic Mesh Products.

122. At all times material hereto, Defendants knew and recklessly disregarded the fact that the Defendants' Pelvic Mesh Products cause debilitating and potentially lethal side effects with greater frequency than safer alternative methods products and/or procedures and/or treatment.

123. At all times material hereto, Defendants knew and recklessly disregarded the fact that the Defendants' Pelvic Mesh Products cause debilitating and potentially lethal side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise the FDA of same.

124. At all times material hereto, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the risk of injuries caused by the Defendants' Pelvic Mesh Products.

125. Notwithstanding the foregoing, Defendants continue to aggressively market the Defendants' Pelvic Mesh Products to consumers, without disclosing the true risk of side effects where there were safer alternatives.

126. Defendants knew of the Defendants' Pelvic Mesh Products defective and unreasonably dangerous nature, but continued to manufacture, produce, assemble, market, distribute, and sell the Defendants' Pelvic Mesh Products so as to maximize sales and profits at

the expense of the health and safety of the Public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by the Defendants' Pelvic Mesh Products.

127. Defendants continue to intentionally conceal and/or recklessly and/or grossly negligently fail to disclose to the public, including Plaintiff, the serious side effects of the Defendants' Pelvic Mesh Products in order to ensure continued and increased sales.

128. Defendants' intentionally reckless and/or grossly negligent failure to disclose information deprived Plaintiff of necessary information to enable them to weigh the true risks of using the Defendants' Pelvic Mesh Products against their benefits.

129. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has required and will require health care and services, and has incurred medical, health care, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical care and/or hospital care and medical services.

130. Defendants have engaged in conduct entitling Plaintiff to an award of punitive damages in that Defendants acted with malice, fraud, gross negligence, or oppressiveness which was not the result of a mistake of fact or law, honest error or judgment, over zealousness, mere negligence, or other human failing with reckless and/or heedless disregard for the consequences, including the safety and health of the Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

i. Compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health and medical care costs, together with interest and costs as provided by law;

ii. Reasonable attorneys' fees;

iii. The costs of these proceedings;

iv. All ascertainable economic damages;

v. Punitive damages; and

vi. Such other and further relief as this Court deems just and proper.

PLAINTIFF DEMANDS A TRIAL BY JURY.

Dated: July 3, 2013

Respectfully submitted,

By: /s/Les Weisbrod

MILLER WEISBROD, LLP
Les Weisbrod
Texas Bar No. 21104900
Alexandra Boone
Texas Bar No. 00795259
Luke Metzler
Texas Bar No. 24072902
11551 Forest Central Drive, Suite 300
Dallas, Texas 75243
214-987-0005
214-987-2545 – FAX
ATTORNEYS FOR PLAINTIFF